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ABSTRACT:

Disclosed is a self-occluding cannula assembly comprising a cannula sheath (34) having a connector hub (46) formed on one end thereof. A self-actuating occluding means (48) is formed within the cannula assembly so as to prevent back flow of body fluids from the cannula. In the cannulae wherein an introducer needle (68) is initially axially positioned within the cannula lumen, the occluding means will permit desired withdrawal of the needle but will thereafter immediately occlude the cannula lumen to prevent back flow therethrough. The occluding means is further adapted to shift to a "non-occluded" configuration upon connection of a second infusion or monitoring tube to the proximal end of the cannula. If, during use, the infusion/monitoring tube should become disconnected, the occluding means will again shift to its "occluded" configuration so as to prevent back flow of fluids from the cannula until such time as the infusion/monitoring line is reconnected.

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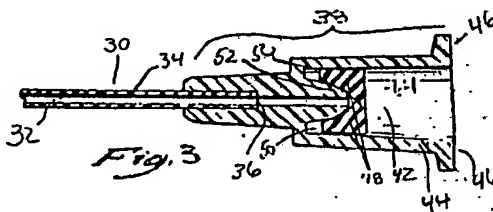
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⑤ Self-occluding intravascular cannula assembly.

⑦ Disclosed is a self-occluding cannula assembly comprising a cannula sheath (34) having a connector hub (46) formed on one end thereof. A self-actuating occluding means (48) is formed within the cannula assembly so as to prevent back flow of body fluids from the cannula. In the cannulae wherein an introducer needle (68) is initially axially positioned within the cannula lumen, the occluding means will permit desired withdrawal of the needle but will thereafter immediately occlude the cannula lumen to prevent back flow therethrough. The occluding means is further adapted to shift to a "non-occluded" configuration upon connection of a second infusion or monitoring tube to the proximal end of the cannula. If, during use, the infusion/monitoring tube should become disconnected, the occluding means will again shift to its "occluded" configuration so as to prevent back flow of fluids from the cannula until such time as the infusion/monitoring line is reconnected.



Description

SELF-OCCLUDING INTRAVASCULAR CANNULA ASSEMBLY

BACKGROUND OF THE INVENTION

This application pertains generally to the medical arts and more particularly to an improved self-occluding cannula assembly for insertion into blood vessels or various body cavities.

The invention is particularly applicable to flexible intravascular cannulae of the type commonly used to administer intravenous infusions and/or to monitor pressures within arteries and/or veins of the human body. Accordingly, the invention will be described with particular reference to such applications. It must be appreciated, however, that the invention has utility in numerous other applications wherein it is desirable to prevent or limit back flow of bodily fluids from a tubular cannula. Examples of other types of cannulae wherein the present invention may be utilized include, but are certainly not limited to; trocars for intra-abdominal or intra-thoracic insertion; long flexible catheters used for monitoring central venous pressures and for centrally administering drugs and various infusates; and various indwelling semi-permanent catheters such as the type commonly used in the administration of total parenteral alimentation.

Although many of the cannulae in which the invention will be used may incorporate removable introducer needles or stylets to effectuate puncture of soft tissues, it must be further appreciated that the utility of the invention is not limited to such needle-bearing devices. In fact, the occluding means of the present invention may be employed with even the simplest types of medical tubing to prevent back flow of fluids therefrom.

It is common practice in the medical field to insert tubular cannulae into blood vessels for the infusion of various fluids and/or the monitoring of intravascular pressures. One simple intravenous cannula assembly of the prior art comprises a flexible cannula sheath having a rigid introducer needle positioned axially therewithin. The bevelled tip of the hollow introducer needle extends a short distance beyond the distal tip of the cannula to permit easy penetration of the skin and underlying tissues. When the needle tip enters the target blood vessel, blood immediately fills the lumen of the needle and advances proximally to a transparent receptical on the needle hub where it may be readily viewed. Alternatively the needle hub may be connected to a syringe wherein a small amount of the blood may be visibly withdrawn into an existing quantity of saline solution. Thereafter, the introducer needle is withdrawn. Thus, the cannula sheath remains in place as a means for subsequent infusion of intravenous fluids and/or monitoring of intravascular pressures.

Because the flexible cannula sheath comprises a generally hollow tube, blood will rapidly back flow (i.e. flash back) through the inner lumen of the cannula upon withdrawal of the introducer needle.

As a result, a certain amount of blood invariably flows out of the proximal end of the cannula immediately after withdrawal of the introducer needle. Regardless of how adept the user may be at attaching an appropriate solution administration line or other auxiliary tube to the proximal end of the cannula, a certain amount of blood loss is likely to occur.

Likewise, if the attendant solution administration line or other tube subsequently becomes disconnected from the cannula, blood will immediately back flow from the cannula and may continue to flow therefrom until the disconnected line is discovered and reconnected.

Indeed, any unnecessary back flow of blood from the cannula lumen is undesirable from a standpoint of general hygiene as well as in view of the present potential for blood born disease transmission. Serious diseases such as Hepatitis and Acquired Immune Deficiency Syndrome are known to be transmissible to health care workers and others who come in contact with infectious blood.

Thus given the desirability of preventing the unnecessary back flow and leakage of blood from the cannula, a number of arrangements have been devised whereby the user of the cannula may pinch off or otherwise obstruct the cannula lumen. Examples of such prior art devices are found in United States Patents No. 3,875,935 (Mellor), 2,682,874 (Hickey), 4,192,304 (Millett), 3,856,020 (Kovac), and 3,856,010 (Moorehead). These prior United States Patents disclose various means for valving, blocking, clamping, pinching, or otherwise restricting certain types of medical tubing for purposes of preventing fluid back flow therefrom.

Specifically, United States Patent No. 4,192,304 (Millett) describes an intravascular catheter assembly comprising a pliable cannula sheath, having an introducer needle disposed axially therewithin. A pair of laterally extending external wings are formed on the proximal end of the cannula. One of the wings bears a pinching protuberance. Upon withdrawal of the introducer needle, the user of the cannula may manually fold one of the wings over the cannula body so as to cause the pinching protuberance to exert occluding pressure on the cannula. Thus, so long as pressure is applied to the folded wing, the pinching protuberance will effectively occlude the cannula lumen. Such occlusion is purported to prevent undesirable back flow of fluids from the cannula.

Another exemplary prior art device is described in United States Patent No. 3,856,010 (Moorehead). The device described therein comprises a flexible cannula sheath having an introducer needle disposed axially therewithin. The Moorehead further incorporates a resilient means which is manually compressable to control the flow of fluid through the cannula. As the introducer needle is withdrawn, the user must positively and affirmatively apply pressure to a projection, which upon passage of the needle,

results in closure of a valve member so as to prevent the flow of fluid through the cannula lumen. Upon release of such pressure, the valve member relaxes, and the cannula lumen resumes its normal shape permitting free fluid flow therethrough.

Yet another exemplary prior art device is disclosed in United States Patent No. 3,875,938 (Mellor). The Mellor device includes a bifurcated cannula assembly wherein a needle-like "puncture rod" is disposed axially within a flexible cannula sheath. The Mellor device includes a means whereby the user may pinch off the cannula lumen between the time that the "puncture rod" is removed and the subsequent coupling of auxiliary infusion tubing to the proximal end of the cannula.

At least one other intravenous cannulation device of the prior art employs a bifurcated design wherein a separate side arm or secondary infusion port is provided in addition to a proximal extension of the lumen through which the introducer needle is withdrawn. The introducer needle may thus be withdrawn through a latex membrane, flap-like seal, or other sealing closure located separate and apart from the side arm infusion port. Thereafter, the infusion of fluid, withdrawal of blood or monitoring of pressures is carried out through the side arm port while the sealed channel through which the needle was withdrawn remains usable only as a self sealing injection port for the periodic injection of medications, or piggyback administration of a second intravenous fluid.

While each of the prior art devices may indeed be capable of stopping or at least limiting, the back flow of blood from certain types of tubes in certain situations, it must be appreciated that none of the prior art devices provides an occlusion means that is fully self activating (i.e. user passive) so as to automatically halt the flow of fluid through the cannula upon withdrawal of the introducer needle and subsequently capable of re-occluding the cannula upon inadvertent disconnection of any attendant infusion/monitoring line. Indeed, many of the prior art occlusion devices require rather intricate manual manipulation and constant manual attendance in order to effect occlusion of the cannula lumen. Additionally, prior art devices which incorporate elaborate secondary infusion ports, side arms, and other bifurcated arrangements may be expensive to manufacture and confounded with unnecessary complexity in clinical use.

Accordingly, there currently exists a need in the art for a fully self-actuating occlusion means which will serve to passively, automatically occlude the cannula lumen upon withdrawal of an existing introducer needle as well as to subsequently re-occlude the cannula lumen upon inadvertent disconnection of any infusion and/or monitoring line from the proximal end of the cannula. The present invention overcomes these shortcomings of the prior art in addition to providing other advantages over the existing devices.

BRIEF DESCRIPTION OF THE INVENTION

In accordance with the present invention, there is provided a self-occluding intravascular cannula assembly which comprises a pliable cannula sheath having an introducer needle retractably axially disposed therewithin such that the bevelled distal tip of the needle extends slightly beyond the distal tip of the cannula sheath. A connecting hub is formed on the proximal end of the cannula to fluidly connect the cannula to a separate infusion tube or monitoring line. At least one occluding member is positioned within the cannula assembly. Such occluding member is alternately disposable in an "occluded" configuration and a "non-occluded" configuration. In its "occluded" configuration, the occluding member will effect blockage of the inner cannula lumen so as to prevent at least proximally directed flow of fluids from the cannula. In its "non-occluded" configuration, the occluding member will permit free fluid flow through the cannula lumen thereby permitting the desired infusion of fluid and/or the transmission of pressure pulses through the fluid filled cannula. Thus, after the needle/cannula assembly has been inserted to its desired location within a blood vessel, the introducer needle is withdrawn. Thereafter, the occluding member will immediately and automatically assume its "occluded" configuration to prevent backflow of blood from the cannula. Subsequently, when the infusion tubing or other auxiliary tube is connected to the proximal end of the cannula assembly, the physical act of connecting such tube will induce the occluding member to move to its "non-occluded" configuration. Such "non-occluded" configuration will permit distal flow of infusate and/or proximal transmission of pressure pulses through the cannula. Thereafter, if the infusion tubing is purposefully or inadvertently disconnected from the cannula, the occluding member will again automatically assume its "occluded" configuration so as to prevent the back flow and leakage of blood from the cannula until such time as the disconnected tubing has been properly reconnected.

In accordance with another aspect of the invention, the occluding member may be in the form of an elastic obturator member positioned within the cannula hub and alternately disposable in "occluded" and "non-occluded" configurations. Preferably, the obturator member will be generally in the form of a cylindrical disc, having a resiliently openable and closable central aperture extending therethrough. The disc shaped obturator is positioned transversely within the cannula lumen with the introducer needle initially disposed through the central aperture of the obturator such that the resilient body of the obturator member will circumferentially abut the outer surface of the introducer needle. After the tip of the cannula assembly has been inserted into the desired vessel, the introducer needle is withdrawn proximally through the obturator member. Immediately upon withdrawal of the needle, the aperture of the obturator member snaps fully closed so as to effect rapid and complete occlusion of the cannula lumen. Thereafter, the insertion of a male tubing connector into the cannula hub will exert pressure on the obturator member thereby shifting the position of the obturator and

causing the central aperture to become dilated. Such dilation of the central aperture will permit fluid to flow through the cannula lumen as desired. If, however the attached infusion tubing should subsequently become disconnected from the cannula, the elastic obturator member will resiliently spring back to its occluded configuration wherein it will prevent back flow and leakage of blood from the cannula. The obturator member will then remain in such occluded configuration until the infusion tubing has been reconnected to the cannula.

In accordance with a further aspect of the invention, the cannula hub may be in the form of a standard female Leur connector capable of receiving a standard male connector and adapted such that the physical act of inserting the male connector into the female connector will cause the occlusion means of the cannula assembly to shift from its "occluded" position to its "non-occluded" position.

In accordance with even further aspect of the invention, the central aperture of the obturator member may be formed as a pinhole, slit, cross slits or any other openable and closable configuration capable of achieving the desired function.

In accordance with an even further aspect of the invention, the cannula hub may include one or more internally formed dilator projection(s). Such dilator projection is positioned distal to the obturator member and configured to aid in dilating the central aperture of the obturator member as the obturator member is depressed distally into a preformed seating groove. Such dilator projection may be nothing more than a raised nub which is operative to exert pressure on the elastic material of the obturator, thereby spreading or stretching the central aperture causing the previously occluded cannula lumen to become unoccluded and free flowing.

A principal object of the invention is to provide a user passive, self-occluding intravascular cannula which will prevent the back flow of bodily fluids from the proximal end of the cannula following insertion of the cannula within a desired vessel and until such time as a second tube is firmly connected thereto.

Another object of the invention is to provide a self-occluding intravascular cannula which will automatically assume an "occluded" configuration in the event that the second tube is inadvertently or purposely disconnected therefrom. Such automatic occlusion of the cannula lumen will prevent the inadvertent back flow of blood from the proximal end of the cannula until such time as the infusion and/or monitoring line is reconnected thereto.

Yet another object of the invention is to prevent or minimize the transmission of blood born diseases such as hepatitis and Acquired Immune Deficiency Syndrome to health care workers and others by preventing the unnecessary backflow of blood from an intravascular cannula.

A still further object of the invention is to provide a self-occluding intravascular cannula wherein the occluding means of the cannula circumferentially abutts the outer surface of the introducer needle so as to thoroughly wipe any adherent blood from the needle as it is withdrawn from the cannula.

These and other objects and advantages of the present invention will become apparent to those skilled in the art upon reading the following detailed description and consideration of the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

Figure 1 is a perspective view of a preferred intravascular cannula assembly of the present invention operatively disposed within a blood vessel and having a separate infusion line fluidly connected thereto;

Figure 2 is a longitudinal sectional view of a preferred intravascular cannula assembly of the present invention having an introducer needle axially disposed within the inner lumen of the cannula;

Figure 3 is a longitudinal sectional view of a preferred intravascular cannula assembly of the present invention wherein the occluding means is disposed in its "occluded" configuration;

Figure 4 is a longitudinal sectional view of a preferred intravascular cannula of the present invention wherein the occluding means is in its "non-occluded" configuration and an attendant infusion line is connected to the cannula assembly;

Figure 5 is an exploded cross-sectional view of selected internal components of a preferred intravascular cannula assembly of the present invention;

Figure 6 is a modified obturator type occluding member having annular grooves formed in the outer periphery thereof to facilitate transition of the obturator between the "non-occluded" and "occluded" positions;

Figure 7 is a longitudinal sectional view of the modified obturator disc of Figure 6 positioned over a dilator member within the catheter assembly as the male Leur connector of a fluid infusion line is being advanced against the obturator member.

DESCRIPTION OF A PREFERRED EMBODIMENT

Referring to Figure 1, there is shown a self occluding intravascular cannula assembly 10 of the present invention inserted into a vein of the human subject. An infusion tube 12 is connected to the cannula assembly 10 by way of a conventional male luer connector 20 so as to provide for continuous administration of the desired infusate.

The intravascular cannula assembly 10 comprises a flexible tube-like sheath shown in dotted lines, which has been inserted percutaneously into the desired vein. A proximal hub 16 forms a portion of the cannula assembly 10. As shown, the hub 16 of the cannula assembly 10 comprises a mating female Leur connector, having a Leur lock flange 18 extending peripherally therearound.

One important feature of the present invention is

the ability of the cannula assembly 10 to "self-occlude." Such self-occlusion prevents the undesirable back flow and leakage of blood from the cannula following retraction of the introducer needle, and also prevents such back flow and leakage of blood in the event that the attendant infusion line 12 is inadvertently or accidentally detached from the cannula assembly 10.

A preferred means by which such self-occluding feature may be formed within the cannula assembly 10 may be fully appreciated from the longitudinal sectional views shown in Figures 2 through 4. Figures 2 through 4 commonly show a portion of the flexible tubular cannula 30 having an inner lumen 32 and an outer tubular wall 34. The outer wall 34 of the cannula 30 is formed of a flexible, physiologically inert material such as polytetrafluoroethylene. The proximal tip 36 of the flexible cannula sheath 34 is firmly fused within the body of the proximal hub 38. The body of the hub is formed of a medical grade molded plastic material which is generally more rigid than the flexible material which forms the cannula sheath 34. The inner lumen 32 of the cannula assembly 10 extends beyond the proximal end 36 of the flexible sheath 34 and continues proximally through a portion of the body of the cannula hub 38 and into the open bore 42 of the hub 38.

A female Leur connector 44 is formed on the proximal end of the hub 38. The inner bore 42 of the female connector 44 portion of the hub 38 is configured to accommodate a corresponding male Leur connector of the type commonly affixed to intravenous solution administration tubes or other types of infusion/monitoring lines. A Leur-lock flange 46 extends peripherally around the proximal end of the female Leur connector 44 so as to accommodate an appropriately threaded locking fixture which may optionally be formed on the corresponding male connector.

The self-occluding feature of the present invention is owed, in this preferred embodiment, to the presence of a specifically formed and positioned occluding means or valving member. In this preferred embodiment, the occluding means comprises an elastomeric or resilient obturator member 48 which is disposed within the cannula hub 38. The obturator member 48 is generally seated within a positioning groove 50 which extends around a conical dilator projection 52. The inner lumen 32 of the cannula assembly 10 extends fully through the dilator projection 52 as shown. A major conical shaped aperture 80 is formed on the distal side of the obturator member 48 so as to permit the member 48 to seat generally over the conical dilator projection 52. As will be further described herein, it is the interaction of the dilator projection 52 with the elastic obturator member 48 which, in part causes the cannula assembly of the present invention to shift from its "occluded" configuration to its "non-occluded" configuration.

Referring specifically to Figure 2, it will be appreciated that, prior to insertion of the cannula into the desired vessel, an introducer needle 60 is axially disposed within the cannula lumen 32 such that the bevelled tip of the needle 60 protrudes

slightly beyond the distal end of the flexible cannula sheath 34. The proximal hub 62 of the needle 60 is sized and configured to fit slidably within the inner bore 42 of the female Leur connector 44 thereby holding the needle 60 and cannula assembly 10 in firm union during insertion into a desired vein. After the cannula assembly 10 (with the introducer needle 60 positioned therein) has been inserted into the desired blood vessel, the needle 60 is withdrawn, leaving the flexible cannula sheath 30 in place within the blood vessel. As the needle 60 is withdrawn, the obturator 48 will wipe any adherent blood from the outer surface of the needle 60. Immediately upon withdrawal of the needle 60, the central aperture 64 of the obturator member 48 will close due to its internal resiliency, thereby preventing back flow of blood from the cannula. The obturator member 48 will remain in such occluded position until such time as the male connector 16 of an attendant infusion line has been fully inserted within the bore 42 of the cannula hub 38. Such insertion of a male connector 16 into the cannula hub 38 will exert distally directed pressure causing the obturator 48 to move distally within the seating groove so causing resultant dilation of the aperture 60 as will be further described herein.

The "occluded" configuration assumed by the obturator 48 upon withdrawal of the needle 60 is shown specifically in Figure 3. With the needle 60 having been fully withdrawn from the cannula lumen 32, the pinhole aperture 64 of the resilient obturator 48 assumes a fully closed configuration so as to occlude the proximal end of the cannula lumen 32 and to prevent the back flow of blood therefrom.

Complete and rapid closure of the aperture 64 is facilitated by the specific positioning of the obturator 48. As shown in Figure 3, the base of the obturator 48 is disposed within an annular seating groove 50. In its unoccluded position the obturator 48 is not fully advanced into the seating groove 50 thereby leaving an unoccupied area or void at the base of the annular seating groove 50. The conical dilator projection 52, which is positioned in the center of the annular seating groove 50, is sized and configured to fit within a corresponding conical notch 80 on the distal side of the obturator 48. So long as the obturator 48 remains in its relaxed position the dilator projection 52 does not exert sufficient proximally directed pressure on the obturator 48 to cause dilation of the aperture 64. It is only when the obturator 48 is depressed distally into its annular seating groove 50 that the conical dilator projection 52 will interact with the obturator 48 to cause dilation and opening of the aperture 64. Such depression of the obturator 48 into the annular groove 50 may be caused by the firm insertion of a male Leur connector 62 into the female bore 42. The manner by which insertion of a male Leur adaptor will cause the obturator to assume its "non-occluded" configuration is shown in Figure 4.

Referring to Figure 4, the tip of the male connector 70 is inserted within the female bore 42 of the female Leur portion 44 of the cannula hub 38. A normal amount of hand pressure is applied distally as the male connector 70 is inserted into the cannula hub.

The resilient obturator 48 is thus forced distally into the previously unoccupied region of its annular seating groove 50. Such distal movement of the resilient obturator 48 causes the conical dilator member 52 to press against and to dilate aperture 64 in the manner shown. Such dilation of the aperture 64 effectively opens the cannula lumen 32 thereby permitting the free flow of infusion fluid through the cannula. It should also be appreciated that while the obturator 48 remains in such "non-occluded" configuration, the cannula lumen will remain sufficiently unobstructed to permit periodic withdrawal of blood or continuous monitoring of pressures through the use of an appropriately connected pressure transducer.

The conical dilator projection 52 and the resilient obturator member 48 are shown in greater detail in the exploded view of Figure 5. As shown in Figure 5, the obturator member 48 comprises a resilient and elastic cylindrical disc made of latex rubber or some other elastomeric material having the requisite elasticity, memory and other physical properties to accomplish the desired objective. The obturator member 48 is a generally cylindrical body having a large conical notch 80 formed within one end of the cylinder and a small conical notch 82 within the opposing end thereof. The apical portions of the two opposing conical notches 80, 82 converge within the center of the disc 48 to form a tiny pinhole aperture 62 extending therebetween. So long as the elastomeric material of the obturator member 48 remains fully relaxed and unstretched the small aperture 62 will be closed sufficiently to prevent the flow of fluid therethrough within the range of intravascular pressures encountered. When, however the elastic material of the obturator 48 is stretched outwardly toward the periphery of the disc, the aperture 62 will become dilated or opened up. Such opening of the aperture 62 effectively relieves the occlusion of the cannula lumen 32 and permits fluid flow there-through.

The large conical notch 80 of the resilient obturator 48 and the annular seating groove 50 may be specifically configured such that the obturator 48 will remain resiliently biased toward its "non-occluded" position. Thus, whenever an existing source of distally directed pressure, such as a properly inserted male connector 70, is removed from its position within the female Luer portion 44 of the cannula hub 38, the resilient obturator 48 will immediately and automatically spring back into its original "occluded" configuration as represented in Figure 3. Such will give rise to rapid self-occlusion of the cannula in the event that the infusion tubing or monitoring line is inadvertently disconnected due to movement of the patient or snagging of the infusion line.

In order to achieve its desired function, the obturator member 48 will be made of a material which is resilient, stretchable, and possessed of sufficient memory to function in the desired manner. In order to accommodate the use of a somewhat dense or slightly incompressible materials, it may be desirable to form a plurality of peripheral notches or grooves around the rim of the disc-like obturator

48. Such notches or grooves will facilitate compaction of the obturator 48 within its seating groove 50 as it shifts from its "non-occluded" to "occluded" configuration. An example of such notch and groove structure is shown in Figures 6 and 7.

Figure 6 shows the modified obturator member 48a which, like its unmodified counterparts, has a large conical notch 80 and small conical notch 82 converging centrally to form tiny pinhole aperture 62. In the view of Figure 6, the modified obturator member 48a is in its fully relaxed "occluded" configuration. The aperture 62 is thus closed. A circumferential groove 90 extends around the mid-region of the periphery of the disc shaped obturator member 48 while a similar right angular cutaway region 92 extends around the distal most portion thereof. The provision of the circumferential groove 90 and the cutaway region 92 serves to reduce the physical mass of the obturator member 48 without interfering with its function. Such grooved construction allows the obturator 48a to be easily compressed into the conical seating groove 50 and also serves to improve the resiliency and proximal bias which causes the obturator 48a to spring back to its non-occluded position immediately upon removal of the male connector from the cannula hub 38.

Figure 7 shows the modified obturator member 48a in its "occluded" configuration wherein the aperture 62 of the modified obturator 48a is fully relaxed in its "occluded" configuration resulting in full closure of the lumen 32. However, as shown, the distal tip of a corresponding male connector 70 is being advanced in the direction of arrow A and is about to come in contact with the modified obturator member 48a. Upon making such contact, and exerting distally directed pressure on the modified obturator member 48a, the member 48a will be slidably depressed over the conical dilator projection 52 as indicated by arrow B. Such will result in a dilation of the aperture 52 relieving the previous occlusion of the cannula lumen 32.

It should be appreciated from these drawings that the self-occluding cannula assembly of the present invention has many advantages. For example, because the aperture 64 of the obturator member 48, 48(a) fits snugly around the introducer needle 60 while it is withdrawn from the cannula lumen 32, such will have the desirable effect of wiping blood from the outer walls of the needle as it is being withdrawn from its position within the cannula lumen. Such blood wiping effect will further limit the potential for transmission of blood born infections.

Also, because the obturator member 48, 48a serves to immediately seal off the cannula lumen upon withdrawal of the introducer needle or detachment of any attendant infusion/monitoring line, the inner bore of the cannula hub will tend to remain clean and free of blood. Such is desirable in that leakage of blood into the bore 42 of the connector 44 could lead to the formation of clots and incrustations around the walls of the bore 42. The presence of such clots or incrustations within the bore 42 may serve to harbor bacteria and, if carried into the cannula lumen, could result in the inadvertent introduction of small emboli.

Additionally, it must be appreciated that the invention has been described herein with reference to a presently preferred embodiment. Indeed, numerous modifications and alternations may be made to such preferred embodiment without departing from the spirit and scope of the invention. For example, in the preferred embodiment, the occluding means which serves to occlude the cannula lumen is specifically described as a resilient obturator member 48, 48a. In alternative embodiments, other types of diaphragms, plugs, valves, flaps, and the like may be utilized in place of the obturator member which has been described with respect to this preferred embodiment. Also, the preferred embodiment is specifically described as an "intravenous cannula" having an introducer needle disposed therein. However, the invention may be incorporated into many other types of tubes, catheters, trocars and the like. Accordingly, it is intended that all such modification and alterations be included within the scope of the appended claims and the equivalents thereof.

Claims

1. A self-occluding cannula assembly comprising:

A flexible cannula sheath having a proximal end, a distal end and an inner lumen extending axially therethrough;

a connecting hub formed on the proximal end of said cannula sheath; and

an occluding means positioned within said connecting hub and alternately disposable between a first "occluded" configuration wherein the occluding means serves to prevent at least proximally directed flow of fluid through the cannula lumen, and a second "non-occluded" configuration wherein the occluding means permits at least distally directed flow through the cannula lumen.

2. The self-occluding cannula assembly of Claim 1 wherein the occluding means comprises an elastic obturator member having an elastically openable and closable aperture extending therethrough, said obturator being sized, configured and positioned such that when said aperture is closed fluid flow through the cannula lumen will be prevented and when said aperture is open fluid flow through the cannula lumen will be permitted.

3. The self-occluding cannula assembly of Claim 1 wherein the cannula assembly further comprises;

an introducer needle having a bevelled distal tip, a proximal end and an outer surface, said introducer needle being slidably axially disposed within the cannula lumen such that the bevelled distal tip of the needle extends beyond the distal tip of the flexible cannula sheath.

4. The self-occluding cannula assembly of Claim 3 wherein the introducer needle is positioned to interact with the occluding means such that the occluding means will rapidly

assume its first "occluded" configuration upon proximal withdrawal of the introducer needle from its initial position with the cannula assembly.

5. The self-occluding cannula assembly of Claim 3 wherein the introducer needle comprises a generally hollow needle having an open, axially extending inner lumen through which blood may flow upon insertion of the distal tip of the needle into a blood vessel.

6. The self-occluding cannula assembly of Claim 3 wherein the occluding means is further operative to circumferentially wipe adherent blood from the outer surface of the introducer needle as it is proximally withdrawn from its initial position within the cannula assembly.

7. The self-occluding cannula assembly of Claim 1 wherein at least a portion of the cannula hub is configured in the form of a female connector having an inner bore into which a correspondingly shaped male tubing connector may be inserted and frictionally retained.

8. The self-occluding cannula assembly of Claim 7 wherein the cannula assembly is functionally adapted such that insertion of the male tubing connector into the female connector of the cannula hub will cause the occluding means to shift from its "occluded" configuration to its "non-occluded" configuration.

9. The self-occluding cannula assembly of Claim 8 wherein the cannula assembly is further functionally adapted such that removal of a previously inserted male tubing connector from its position within the female connector of the cannula hub will cause the occluding means to shift from its "non-occluded" configuration to its "occluded" configuration.

10. The self-occluding cannula assembly of Claim 1 further comprising;

a dilator projection sized, configured and positioned to interact with said occlusion means, thereby assisting in the transition of said occlusion means from said "occluded" configuration and to said "non-occluded" configuration.

11. The self-occluding cannula assembly of Claim 2 further comprising;

a dilator projection sized, configured and positioned to selectively interact with the elastic obturator member, thereby selectively exerting pressure about the elastically openable and closable aperture so as to assist in the alternate opening and closing of said aperture.

12. The self-occluding cannula assembly of Claim 2 wherein an obturator seating groove is formed with the cannula hub, said obturator seating groove being sized and configured to receive at least a portion of said obturator member therewithin.

13. The self-occluding cannula assembly of Claim 12 wherein said obturator member is only partially seated within said seating groove while the cannula assembly is in its "occluded" configuration but fully seated within said seating groove when in its "non-occluded" configuration.

ration.

14. The self-occluding cannula assembly of Claim 13 wherein;

said cannula assembly further comprises a generally conical dilator projection having a round base and a blunt apex with an obturator seating groove formed annularly about the round base of said dilator projection.

15. The self-occluding cannula assembly of Claim 14 wherein said obturator member comprises a cylindrical disc-shaped structure formed of elastomeric material and having a first generally conical notch formed therein, said first generally conical notch being substantially analogous in configuration to the configuration of the dilator projection and positioned thereover such that while said cannula assembly is in its "occluded" configuration, the blunt apex of the dilator projection will be partially advanced into said conical notch and, when said cannula assembly is in its "non-occluded" configuration the blunt apex of the dilator projection will be fully advanced into said conical notch so as to facilitate opening of said aperture by exerting outward pressure on said elastic obturator member.

16. A self-occluding cannula assembly com-

prising;

a generally tubular cannula body having a proximal end, a distal end, and an axially extending inner lumen;

a tubing connector formed on the proximal end of the cannula, said tubing connector being operative to fluidly connect said cannula to a separate tube;

at least one occluding means positioned within the assembly, said occluding means being alternately disposable between an "occluded" configuration and a "non-occluded" configuration, wherein said occluded configuration is operative to block said inner lumen so as to prevent back flow of bodily fluids from the proximal end of said cannula and said non-occluded configuration is operative to permit fluid infusion distally through said cannula; and said cannula assembly being sized, configured and constructed such that the physical act of connecting a separate tube to the said tubing connector will cause said occluding means to assume its "non-occluded" configuration while the disconnection of said separate tube from said tubing connector will allow said occluding means to assume its occluded configuration.

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Fig. 1

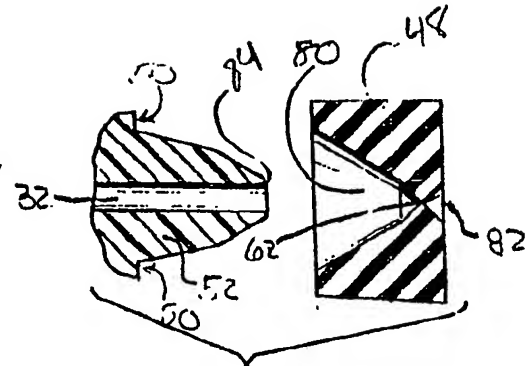
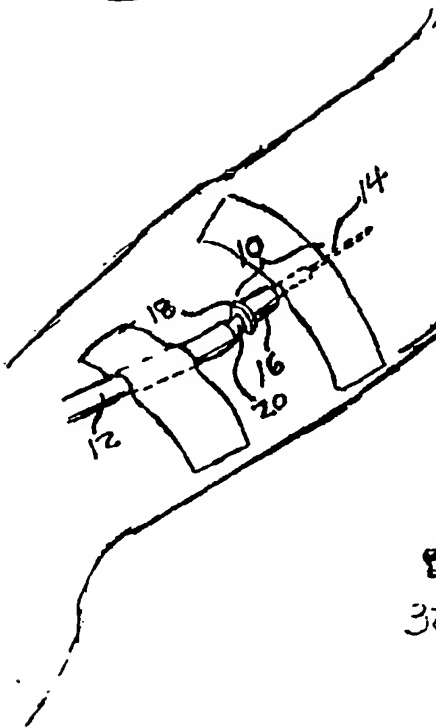


Fig. 5

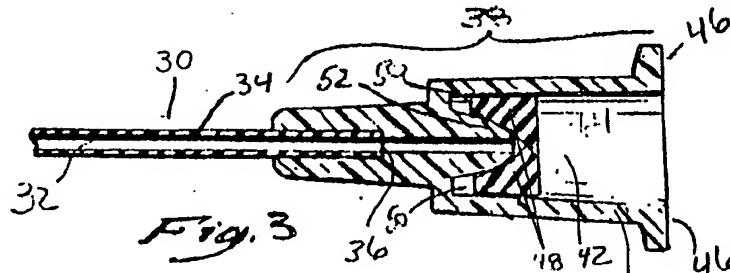


Fig. 3

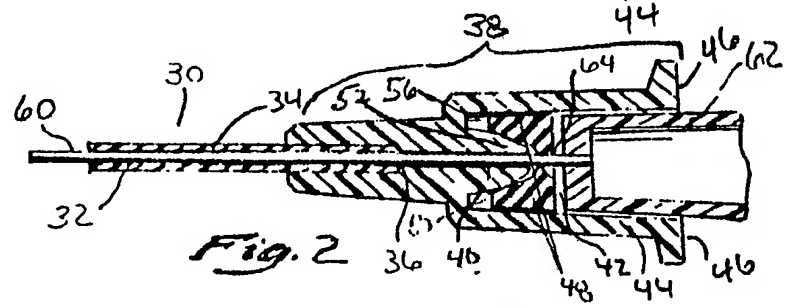


Fig. 2

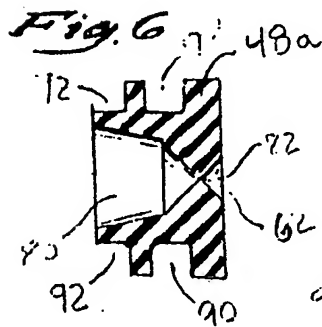


Fig. 6

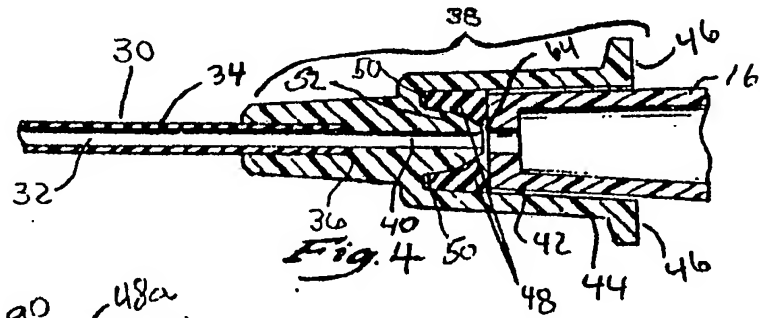


Fig. 4

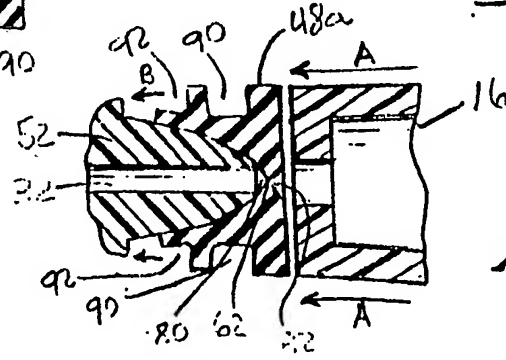


Fig. 7



European Patent
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EUROPEAN SEARCH REPORT

Application Number

EP 89 30 5245

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 4)
X	FR-A-2 439 022 (VIGGO AB) * Page 3, lines 12-33; page 6, lines 5-14; page 6, line 36 - page 7, line 2; page 7, lines 22-24; figures 1-7 * ---	1,3-7	A 61 M 37/00
X	DE-A-2 830 800 (METATECH CORP.) * Page 9, line 21 - page 10, line 10; page 15, lines 16-27; figures 1-6 * -----	1-2,7-9,16	
			TECHNICAL FIELDS SEARCHED (Int. Cl. 4)
			A 61 M F 16 K F 16 L
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 18-08-1989	Examiner MIR Y GUILLEN V.
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